Human Med Ag
% Tuv Sud America Inc.
Stefan Preiss
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

June 8, 2021

Re: K082025
Trade/Device Name: Body-Jet
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Stefan Preiss:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 13, 2008. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Human Med AG
% TUV SUD America, Inc.
Stefan Preiss
1775 Old Highway 8 NW
New Brighton, Minnesota 55112

AUG 13 2008

Re: K082025
Trade/Device Name: body-jet®
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MVV
Dated: July 28, 2008
Received: July 30, 2008

Dear Stefan Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082025

Device Name: body-jet®

Indications for Use:

Aesthetic body contouring

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082028

Prescription Use (Part 21 CFR 801 Subpart D) yes AND/OR Over-the-Counter Use (21 CFR 801 Subpart C) no

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AUG 13 2008

This 510(k) Summary for body-jet® meets the requirements of 21 CFR § 807.92

1. Submitter Information

Human Med AG
Wilhelm-Hennemann-Strasse 9
D-19061 Schwerin
Germany

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2. Name of Device:

Common name: Suction Lipoplasty System

Proprietary name: body-jet®

Classification: Suction Lipoplasty System, Class II, 21 CFR § 878.5040

Product code: MUU

Indications for use: Aesthetic body contouring

3. Name of the predicate device(s)

- Liposat® Power Infiltration Pump (Model 00002274)
  Moeller Medical GmbH & Co. KG
  (K053451)
- Dominant 50 Lipo Powered Suction Pump,
  Medela AG
  (K063336)
- Byron Medical Infiltration and Aspiration Cannulae and Needles
  Byron Medical, Inc.
  (K981172)

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4. Device Description

The body-jet®, a suction lipoplasty system, is a device intended for aesthetic body contouring. The device consists of a powered vacuum pump (containing an overflow/bacterial filter in the tube between the vacuum pump and suction bag), a collection bag with integrated overflow/bacterial filter, cannulae, and a connecting tube. The suction/collection bags including bacterial filters, the tubing, and the cannulae are to be changed between patients.
The powered vacuum pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 26.5 inches of mercury, vacuum control valve to regulate the vacuum with accompanying vacuum gauge, a double piston, and a safety trap. The powered vacuum pump generates a negative pressure for the removal of fat or adipose tissue from distinct body-fat deposits for aesthetic body-contouring.

The body-jet® includes a sterile, single-use tubing set with a small infiltration pump (the WAL Applicator), which transports the saline for the infiltration of the tissue area to be treated, and infiltration and irrigation/aspiration cannulae. The single-use tubing set (WAL Applicator) and the reusable cannulae have been designed as proprietary products.

5. Indications for Use

The body-jet® is intended for aesthetic body contouring.

6. Summary of Technological Characteristics

The body-jet® vacuum pump system consists of a powered vacuum pump with two WOB-L pistons (dynamic compression by fixed piston inside cylinder) working bit-parallel in the pump. The powered vacuum pump generates a negative pressure for the removal of adipose tissue. Two suction containers of identical design and mode of operation, one on the left side and one on the right side of the body-jet® device, are provided for holding the suction bags.

The suction bags are equipped with a dual-function filter valve. The filter acts simultaneously as an overflow protection and a bacterial barrier and closes automatically when it comes in contact with fluids. The connecting tube between the collection bag and the vacuum pump contains an overflow protection/bacterial filter. It is used when the dual filter in the suction bag is damaged. If the fluid reaches a maximum level in the bag, the floats in the overflow filter will block the inlet port, automatically stopping the suction. This prevents the back-up of fluid to either the pump or the patient. The tubing is able to withstand the amount of negative pressure created by the vacuum pump without collapsing.
A small infiltration pump (included in the single-use WAL Applicator) transports the saline for the infiltration of the treated tissue area via the infiltration/aspiration cannulae, similar to the procedure of traditional liposuction and of its predicate devices. The WAL Applicator has been designed as a single-use proprietary product. The cannulae are re-sterilizable proprietary products.

The vacuum pump system, the infiltration pump system and the cannulae of the body-jet® are substantially equivalent to the vacuum and infiltration pump systems, and the cannulae of its predicate devices in terms of intended use, design, operating principles, and materials.

7. Summary of Histopathological and Immunohistological Performance Data

In order to support a determination of safety and effectiveness, the effect of the fan-shaped saline spray of the body-jet® has been studied on different human tissue structures. For this purpose two **in-vitro laboratory investigations** have been carried out. on fat tissue samples from human corpses (Investigation 1), and from "dead" abdominal fat excisates (Investigation 2). No humans have been treated for the purpose of these in-vitro laboratory investigations.

The following tissue structures were examined: :

- adipose tissue,
- connective tissue,
- muscle tissue,
- blood vessels,
- nerves.

Based on the results of these investigations (please refer to Section 18) it can be summarized that water assisted lipoplasty with the fan-shaped water spray of the body-jet® produces no damage to vital structures like connective tissue, muscle tissue, blood vessels and nerves, thus supporting a determination of safety and substantial equivalence of the body-jet® water-assisted technique WAL to its predicate devices and the other referenced lipoplasty techniques.

8. Summary of Clinical Performance Data

The evaluation of **published clinical performance** data demonstrate that the body-jet® device is as safe, as effective, and performs as well as its predicate devices and the other referenced lipoplasty techniques that are currently cleared for aesthetic body contouring.

Based on the results of the published clinical performance data (as presented in Section 20) and the pathohistological performance data (as presented in Section 18) it can be summarized that water assisted lipoplasty with the fan-shaped water spray of the body-jet® loosens the adipose tissue, and separates and aspirates the adipocytes without producing any damage to vital structures like connective tissue, muscle tissue, blood vessels and nerves, thus supporting a determination of safety and effectiveness, and substantial equivalence of the body-jet® water-assisted technique (WAL) to its predicate devices and the other referenced lipoplasty techniques.

9. Conclusion

Based upon the information presented above and in this 510(k) submission , it is concluded that the proposed body-jet® is substantially equivalent to its predicate devices, and safe and effective for the intended use of aesthetic body contouring.